

We Claim:

1. A film coated tablet comprising:
 - (a) at least 50% by weight of a dried aqueous extract of red vine leaves;
 - (b) up to 50% by weight of an excipient consisting essentially of: at least one binder, at least one disintegrant, at least one filler, and a lubricant; and
 - (c) a tablet film consisting essentially of: a film former, a plasticizer, a coating agent, and optionally a coloring agent.
2. The film coated tablet of claim 1, wherein the dried aqueous extract of vine leaves further comprises an addition of up to 10% by weight of silica based on total amount of component (a).
3. The film coated tablet of claim 2, wherein the silica is colloidal, anhydrous silica.
4. The film coated tablet according to claim 1, comprising:
 - (a) 50% to 70% by weight of the dried aqueous extract of red vine leaves;
 - (b) 25% to 49% by weight of the excipient; and
 - (c) 1% to 5% by weight of the tablet film,based on the total mass of the film coated tablet.
5. The film coated tablet according to claim 1, comprising:
 - (a) 51% to 59% by weight of the dried aqueous extract of red vine leaves;
 - (b) 38% to 48% by weight of the excipient; and
 - (c) 1 to 3% by weight of the tablet film,based on the total mass of the film coated tablet.
6. The film coated tablet according to one of claims 1 to 5, wherein the excipient (b) consists essentially of: 70% to 85% by weight of at least one binder, 0.5% to 12.5% by weight of at least one disintegrant, 5% to 15% by weight of at least one filler, and 1% to 5% by weight of at least one lubricant, based on the total mass of the excipient (b).

7. The film coated tablet according to one of claims 1 to 5, wherein the binder is powdered cellulose, microcrystalline cellulose, starch, polyvinylpyrrolidone, copolymers of vinylpyrrolidone with other vinyl derivatives, cellulose derivatives, or a mixture thereof.
8. The film coated tablet according to claim 6, wherein the binder is powdered cellulose, microcrystalline cellulose, starch, polyvinylpyrrolidone, copolymers of vinylpyrrolidone with other vinyl derivatives, cellulose derivatives, or a mixture thereof.
9. The film coated tablet according to one of claims 1 to 5, wherein the disintegrant is colloidal silica, sodium starch glycolate, crosslinked polyvinylpyrrolidone (crospovidone), croscarmellose sodium salt (sodium salt of cellulose carboxymethyl ether, crosslinked), sodium-carboxymethylcellulose, dried maize starch, or a mixture thereof.
10. The film coated tablet according to claim 6, wherein the disintegrant is colloidal silica, sodium starch glycolate, crosslinked polyvinylpyrrolidone (crospovidone), croscarmellose sodium salt (sodium salt of cellulose carboxymethyl ether, crosslinked), sodium-carboxymethylcellulose, dried maize starch, or a mixture thereof.
11. The film coated tablet according to one of claims 1 to 5, wherein the filler is an inorganic phosphate or hydrogen phosphate.
12. The film coated tablet according to claim 6, wherein the filler is an inorganic phosphate or hydrogen phosphate.
13. The film coated tablet according to one of claims 1 to 5, wherein the filler is silicon dioxide, talc, stearic acid, sodium stearyl fumarate, magnesium stearate, or glycerol tribehenate.
14. The film coated tablet according to claim 6, wherein the filler is silicon dioxide, talc, stearic acid, sodium stearyl fumarate, magnesium stearate, or glycerol tribehenate.

15. The film coated tablet according to one of claims 1 to 5, wherein the tablet film (c) consists essentially of: 50% to 85% by weight of at least one film former, 5% to 10% by weight of at least one plasticizer, 10% to 20% by weight of at least one coating agent, and 0% to 15% by weight of at least one colorant, based on the total mass of the tablet film (c).

16. The film coated tablet according to claim 6, wherein the tablet film (c) consists essentially of: 50% to 85% by weight of at least one film former, 5% to 10% by weight of at least one plasticizer, 10% to 20% by weight of at least one coating agent, and 0% to 15% by weight of at least one colorant, based on the total mass of the tablet film (c).

17. A process for preparing a film coated tablet comprising:

- (a) mixing a dried aqueous extract of red vine leaves with excipients, optionally in the presence of a volatile diluent;
- (b) optionally screening the mixture obtained;
- (c) compressing the mixture with a suitable tablet press; and
- (d) coating the resulting tablet with a tablet film.

18. A method for making a film coated tablet containing a dried aqueous extract of red vine leaves comprising:

- (a) extracting red vine leaves with water and drying the extract to obtain a dried aqueous extract of red vine leaves;
- (b) combining the dried aqueous extract of red vine leaves with an excipient consisting essentially of: at least one binder, at least one disintegrant, at least one filler, and a lubricant;
- (c) forming a tablet of the mixture obtained from step (b); and
- (d) coating the tablet with a tablet film consisting essentially of: a film former, a plasticizer, a coating agent, and optionally a coloring agent to obtain a film coated tablet.

19. The method of claim 18, wherein the dried aqueous extract of vine leaves further comprises an addition of up to 10% by weight of silica based on total amount of the dried aqueous extract of red vine leaves.

20. The method of claim 19, wherein the silica is colloidal, anhydrous silica.

21. The method of claim 20, wherein the colloidal, anhydrous silica is added to the dried aqueous extract of vine leaves during drying or before admixing with the other constituents.

22. A method for making an aqueous extract of red vine leaves comprising:

- (a) collecting red vine leaves at a point of time when the content in flavonoids has reached an optimum;
- (b) drying and crushing the leaves;
- (c) cutting the leaves to pieces;
- (d) extracting the leaves with water at elevated temperatures for 6 to 10 hours; and
- (e) concentrating and drying the aqueous extract of red vine leaves.

23. The method according to claim 22, further comprising adding during the drying process (e) up to 10% by weight of a flow regulator based on the final total amount of the aqueous extract of red vine leaves.

24. The method according to claim 23, wherein the flow regulator is silica.

25. The method according to claim 23, wherein the flow regulator is colloidal, anhydrous silica.

26. The method according to claim 25, wherein the colloidal, anhydrous silica comprises 2.5% to 7.5% by weight based on the final total amount of the aqueous extract of red vine leaves.

27. The method according to claim 26, wherein the colloidal, anhydrous silica comprises about 4% by weight based on the final total amount of the aqueous extract of red vine leaves.

28. The method according to claim 22, wherein the leaves in step (d) are extracted with water at temperatures from 60°C to 80°C.